

## LIST OF EXHIBITS AND WITNESSES

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TREATMENT CENTER, INC.,  
CELL SURGICAL NETWORK  
CORPORATION, ELLIOT B. LANDER, M.D.  
and MARK BERMAN, M.D.

**UNITED STATES DISTRICT COURT  
FOR THE CENTRAL DISTRICT OF CALIFORNIA  
EASTERN DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

v.

CALIFORNIA STEM CELL  
TREATMENT CENTER, INC.,  
*et al.*

Defendants.

No. 5:18-CV-01005-JGB-KKx

Hon. Jesus G. Bernal  
Courtroom 1

**SECOND AMENDED JOINT EXHIBIT  
LIST**

Trial Date: May 4, 2021  
Hearing Time: 9:00 a.m.  
Courtroom: Riverside Courthouse  
3470 Twelfth Street  
Riverside, CA 92501  
Courtroom 1, 2nd Floor

Pursuant to Rule 26(a)(3)(A)(iii) of the Federal Rules of Civil Procedure, and Local Rule 16-6.1, Plaintiff United States of America and Defendants California Stem Cell Treatment Center, Inc., Cell Surgical Network Corporation, Elliot B. Lander, M.D., and Mark Berman, M.D., (“Defendants”), submit this Second Amended Joint Exhibit List in advance of the May 4, 2021 trial.

The parties reserve the right to offer any item listed below, and reserve the right to offer unlisted exhibits for purposes of impeachment or rebuttal. The fact that an item appears on this list as a potential exhibit is not to be construed as a waiver by any of the parties of any objections they may have to its admissibility.

**I. PLAINTIFF’S EXHIBITS** (items in bold denote items of stipulated admissibility)

<b>Ex. No.</b>	<b>Description</b>	<b>Date Identified</b>	<b>Date Admitted</b>
1.	Expert Report of Carolyn Yong, Ph.D.	5/7/2021	
2.	Rebuttal Report of Carolyn Yong, Ph.D.		
3.	Deposition Transcript Excerpts of Carolyn Yong, Ph.D.		
4.	Expert Report of Larissa Lapteva, M.D.		
5.	Rebuttal Report of Larissa Lapteva, M.D.		
6.	Expert Report of Doran L. Fink, M.D., Ph.D.		
7.	Expert Report of Randa Melhem, Ph.D.		
8.	Defendants’ Responses to Rule 36 Requests for Admissions	5/11/2021	5/11/2021
9.	Defendants’ Responses to Rule 33 Interrogatories	5/11/2021	5/11/2021
10.	Screenshots of CSN-CSCTC Website 8-29-17	5/12/2021	5/12/2021
11.	2017 Establishment Inspection Report (“EIR”) for CSCTC Rancho Mirage	5/4/2021	5/4/2021
12.	2017 Establishment Inspection Report (“EIR”) for CSCTC Beverly Hills	5/5/2021	5/5/2021
13.	<b>CSCTC Brochure</b> <i>2017 EIR (Rancho Mirage) Ex. CJ51</i>	5/5/2021	5/5/2021

Ex. No.	Description	Date Identified	Date Admitted
14.	List of Patients Treated at CSCTC Beverly Hills <i>2017 EIR (Beverly Hills) Ex. MF16</i>	5/5/2021	5/5/2021
15.	<b>Protocol - Clinical Intervention Study: Efficacy of Adipose Derived SVF for Degenerative Ophthalmic Conditions</b> <i>2017 EIR (Rancho Mirage) Ex. CJ8</i>	5/4/2021 stip	5/4/2021 stip
16.	<b>Ophthalmic Deployment Instructions</b> <i>2017 EIR (Rancho Mirage) Ex. CJ9</i>	5/4/2021 stip	5/4/2021 stip
17.	Printout of CSN-CSCTC Website Screenshots		
18.	CSN-Time Machine Method for Preparing SVF (2016 and 2017 versions) <i>2017 EIR (Rancho Mirage) Ex. WFL24</i>	5/4/2021	5/4/2021
19.	<b>Steps to Stromal Vascular Fraction PPT Presentation</b> <i>2017 EIR (Rancho Mirage) Ex. CJI</i>	5/4/2021 stip	5/4/2021 stip
20.	<b>Photograph of Syringe of SVF (intermediate)</b> <i>2017 EIR (Rancho Mirage) Ex. WFL35</i>	5/4/2021 stip	5/4/2021 stip
21.	<b>Photograph Showing Syringes of SVF (final prep)</b> <i>2017 EIR (Rancho Mirage) Ex. WFL36</i>	5/4/2021 stip	5/4/2021 stip
22.	<b>Photograph Showing Labeling of Syringes of SVF (final)</b> <i>2017 EIR (Rancho Mirage) Ex. WFL37</i>	5/4/2021 stip	5/4/2021 stip
23.	<b>Photograph Showing Labeling of IV Administration Set</b> <i>2017 EIR (Rancho Mirage) Ex. WFL38</i>	5/4/2021 stip	5/4/2021 stip
24.	<b>Photograph Showing Labeling of IV Administration Set (reverse side)</b> <i>2017 EIR (Rancho Mirage) Ex. WFL39</i>	5/4/2021 stip	5/4/2021 stip
25.	CSN Corporate History Documents <i>2017 EIR (Beverly Hills) Ex. MF3</i>	5/5/2021	5/5/2021
26.	<b>CSN Affiliates Documents</b> <i>2017 EIR (Beverly Hills) Ex. MF4</i>	5/4/2021 stip	5/4/2021 stip
27.	<b>Packing Slip for 5% Dextrose in Lactated Ringer's Injection</b> <i>2017 EIR (Beverly Hills) Ex. DC4</i>	5/4/2021 stip	5/4/2021 stip

Ex. No.	Description	Date Identified	Date Admitted
28.	<b>Photograph of 5% Dextrose in Lactated Ringer's Injection</b> <i>2017 EIR (Rancho Mirage) Ex. WFL32</i>	5/4/2021 stip	5/4/2021 stip
29.	<b>Packing Slip and Certificate of Analysis for Order 293</b> <i>2017 EIR (Beverly Hills) Ex. DC2</i>	5/4/2021 stip	5/4/2021 stip
30.	Photographs of Dextrose, saline (NaCl), operations, equipment and labeling <i>2017 EIR (Beverly Hills) Ex. DC15</i>	5/5/2021	5/5/2021
31.	<b>Sterile Technique</b> <i>2017 EIR (Beverly Hills) Ex. MF17</i>	5/4/2021 stip	5/4/2021 stip
32.	SVF Cultures <i>2017 EIR (Beverly Hills) Ex. MF36</i>	5/5/2021	5/5/2021
33.	Patient Medical Records (MB) <i>2017 EIR (Beverly Hills) Ex. MF15</i>	5/5/2021	5/5/2021
34.	FedEx Tracking for Adipose Tissue Sent to New Jersey Firm <i>2017 EIR (Beverly Hills) Ex. DC1</i>		
35.	Transportation Records for Expanded Cells <i>2017 EIR (Beverly Hills) Ex. MF28</i>	5/5/2021	5/5/2021
36.	Protocol Amendment – Frozen/Thawed SVF and/or Expanded Cells (MSCs) <i>2017 EIR (Rancho Mirage) Ex. WFL49</i>	5/4/2021	5/4/2021
37.	Cells on Ice (COI) SOP Documents <i>2017 EIR (Beverly Hills) Ex. MF10</i>	5/5/2021	5/5/2021
38.	2017 FDA Form-483 (Inspectional Observations) for CSCTC Rancho Mirage	5/4/2021	5/4/2021
39.	2017 FDA Form-483 (Inspectional Observations) for CSCTC Beverly Hills	5/5/2021	5/5/2021
40.	CSN and Cells on Ice Patient Listing at CSCTC RM <i>2017 EIR (Rancho Mirage) Ex. WFL8</i>	5/4/2021	5/4/2021
41.	<b>Photographs of Manufacturing Equipment</b> <i>2017 EIR (Rancho Mirage) Ex. WFL63</i>	5/4/2021 stip	5/4/2021 stip

Ex. No.	Description	Date Identified	Date Admitted
42.	<b>Photograph of Employee Performing Manufacturing Step of SVF</b> <i>2017 EIR (Rancho Mirage) Ex. WFL34</i>	5/4/2021 stip	5/4/2021 stip
43.	<b>Photograph Showing Manufacturing Room Hallway</b> <i>2017 EIR (Rancho Mirage) Ex. WFL40</i>	5/4/2021 stip	5/4/2021 stip
44.	<b>TMAX Certificate of Analysis</b> <i>2017 EIR (Rancho Mirage) Ex. CJ55</i>	5/4/2021 stip	5/4/2021 stip
45.	<b>TMAX Certificate of Analysis</b> <i>2017 EIR (Rancho Mirage) Ex. CJ56</i>	5/4/2021 stip	5/4/2021 stip
46.	<b>Photograph of TMAX</b> <i>2017 EIR (Rancho Mirage) Ex. CJ63</i>	5/4/2021 stip	5/4/2021 stip
47.	Patient S101-015 Medical Records <i>2017 EIR (Rancho Mirage) Ex. CJ32</i>		
48.	<b>Protocol - Clinical Intervention Study: Safety of Autologous Adipose Derived SVF Combined with ACAM2000 (Vaccinia) Vaccine in Patients With Advanced Solid Tumors</b> <i>2017 EIR (Rancho Mirage) Ex. WFL56</i>	5/4/2021 stip	5/4/2021 stip
49.	Adipose SVF Cultures <i>2017 EIR (Rancho Mirage) Ex. CJ57</i>	5/11/2021	5/11/2021
50.	Patient Medical Records (K.R.) <i>2017 EIR (Rancho Mirage) Ex. CJ16</i>		
51.	Serious Adverse Events <i>2017 EIR (Rancho Mirage) Ex. CJ10</i>		
52.	Patient Adverse Event Documents (D.B.) <i>2017 EIR (Rancho Mirage) Ex. CJ12</i>		
53.	Patient Adverse Event Documents (A.C.) <i>2017 EIR (Rancho Mirage) Ex. CJ13</i>		
54.	Patient Medical Records (R.B.) <i>2017 EIR (Rancho Mirage) Ex. CJ20</i>		
55.	Cancer Patient S101-001 Treatment Records (J.Y.) <i>2017 EIR (Rancho Mirage) Ex. CJ25</i>		
56.	Cancer Patient Medical Records (A.H.) <i>2017 EIR (Beverly Hills) Ex. MF34</i>	5/5/2021	5/5/2021

Ex. No.	Description	Date Identified	Date Admitted
57.	Operating Room Check Sheets <i>2017 EIR (Beverly Hills) Ex. DC13</i>	5/5/2021	5/5/2021
58.	<b>Packing Slip for Saline (Sodium Chloride) Solution</b> <i>2017 EIR (Beverly Hills) Ex. DC3</i>	5/4/2021 stip	5/4/2021 stip
59.	Cancer Patient Medical Record (J.Y.) <i>2017 EIR (Beverly Hills) Ex. MF33</i>	5/5/2021	5/5/2021
60.	List of Cancer Patients Treated at CSCTC BH <i>2017 EIR (Beverly Hills) Ex. MF44</i>	5/5/2021	5/5/2021
61.	Patient Medical Records (S.R.) <i>2017 EIR (Beverly Hills) Ex. MF32</i>	5/5/2021	5/5/2021
62.	Adverse Events Post Deployment <i>2017 EIR (Beverly Hills) Ex. MF43</i>	5/5/2021	5/5/2021
63.	Patient Adverse Event Documents (D.T.) <i>2017 EIR (Rancho Mirage) Ex. CJ11</i>	5/11/2021	5/11/2021
64.	Serious Adverse Events (D.V.) <i>2017 EIR (Rancho Mirage) Ex. CJ15</i>		
65.	List of Cancer Patients Treated at CSCTC Facilities <i>2017 EIR (Rancho Mirage) Ex. WFL58</i>	5/4/2021	5/4/2021
66.	FDA Warning Letter to Thomas A. Gionis, Irvine Stem Cell Treatment Center in California		
67.	Defendants' 2013 Interview (Part 1) with Knoepfler Lab Stem Cell Blog re: Cell Surgical Network	5/5/2021	5/5/2021
68.	Defendants' 2013 Interview (Part 2) with Knoepfler Lab Stem Cell Blog re: SVF, FDA, and Homologous Use	5/5/2021	5/5/2021
69.	Defendants' Response to 2017 FDA Form-483 for CSCTC Rancho Mirage	5/6/2021	5/6/2021
70.	Defendants' Response to 2017 FDA Form-483 for CSCTC Beverly Hills	5/6/2021	5/11/2021
71.	Email Correspondence between Dr. Ginette Michaud (FDA) and Defendants in October 2017	5/12/2021	
72.	FDA 2017 Press Release Following Seizure of ACAM2000		



Ex. No.	Description	Date Identified	Date Admitted
73.	CSCTC Press Release Following FDA Seizure of ACAM2000		
74.	Email Correspondence from Defendants to Dr. Ginette Michaud (FDA) in December 2017		
75.	Defendants' 2017 Interview with Knoepfler Lab Stem Cell Blog re: CSN's use of expanded cells	5/5/2021	5/5/2021
76.	<b>Lander Affidavit, dated July 26, 2017 (5 pages)</b> <i>2017 EIR (Rancho Mirage) Attachment - WFL</i>	5/4/2021 stip	5/4/2021 stip
77.	<b>Lander Affidavit, dated July 26, 2017 (4 pages)</b> <i>2017 EIR (Rancho Mirage) Attachment - CJ</i>	5/4/2021 stip	5/4/2021 stip
78.	<b>Protocol - Clinical Intervention Study: Safety and Efficacy of Pentosan Polysulfate Encapsulated in Liposomes for Interstitial Cystitis</b> <i>2017 EIR (Rancho Mirage) Ex. WFL16</i>	5/4/2021 stip	5/4/2021 stip
79.	<b>Protocol - Clinical Intervention Study: Efficacy of Adipose Derived SVF for Degenerative Neurological Conditions</b> <i>2017 EIR (Rancho Mirage) Ex. WFL19</i>	5/4/2021 stip	5/4/2021 stip
80.	<b>Protocol - Clinical Intervention Study: Intracerebroventricular Deployment of SVF</b> <i>2017 EIR (Rancho Mirage) Ex. WFL20</i>	5/4/2021 stip	5/4/2021 stip
81.	<b>Protocol - Clinical Intervention Study: Safety of Autologous Adipose Derived SVF Combined with ACAM2000 (Vaccinia) Vaccine in Patients With Advanced Solid Tumors</b> <i>2017 EIR (Rancho Mirage) Ex. WFL56</i>	5/4/2021 stip	5/4/2021 stip
82.	Adverse Event Records re: SVF/ACAM2000 Safety Study <i>2017 EIR (Rancho Mirage) Ex. WFL60</i>	5/4/2021	5/4/2021
83.	Lander videotaped interview <a href="https://www.youtube.com/watch?v=otushsFxxkzw">https://www.youtube.com/watch?v=otushsFxxkzw</a>		
83a	Transcript of Lander videotaped interview		
84.	Berman video <a href="https://www.youtube.com/watch?v=SVVQrosn0gc">https://www.youtube.com/watch?v=SVVQrosn0gc</a>	5/11/2021	



Ex. No.	Description	Date Identified	Date Admitted
84a	Transcript of Berman video		
85.	CSN FAQ video: What Can Stem Cells Be Used For? <a href="https://www.youtube.com/watch?v=fWi_UzX-i_A">https://www.youtube.com/watch?v=fWi_UzX-i_A</a>		
85a	Transcript of CSN FAQ video: What Can Stem Cells Be Used For?		
86.	Food & Drug Admin., <i>Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception</i> ; Guidance for Industry, Nov. 2017		
87.	Food & Drug Admin., <i>Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use</i> ; Guidance for Industry and Food and Drug Administration Staff, dated Nov. 2017 and corrected Dec. 2017		
88.	Food & Drug Admin., Proposed Approach to Regulation of Cellular and Tissue-Based Products, FDA Dkt. No. 97N 0068 (Feb. 28, 1997)		
89.	Food & Drug Admin., <i>Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products</i> ; Draft Guidance for Industry and FDA Staff, Dec. 2014		
90.	FDA Warning Letter to American CryoStem Corporation in New Jersey	5/4/2021	5/11/2021
91.	* Chapter 6. Adipose Tissue. In: Mescher AL. eds. Junqueira's Basic Histology: Text & Atlas, 15e. New York: McGraw-Hill; 2018. <a href="http://accessmedicine.mhmedical.com/content.aspx?bookid=2430&amp;sectionid=190277324">http://accessmedicine.mhmedical.com/content.aspx?bookid=2430&amp;sectionid=190277324</a> .		
92.	* Brown SA, Levi, B, Lequeux, C, et al. Basic Science Review on Adipose Tissue for Clinicians. <i>Plast. Reconstr. Surg.</i> 126:1936, 2010.		
93.	* Comley K, Fleck NA. The toughness of adipose tissue: measurements and physical basis. <i>Journal of Biomechanics.</i> 2010;43(9):1823-6.		

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94.	* Comley K, Fleck NA. A micromechanical model for the Young's modulus of adipose tissue. International Journal of Solids and Structures. 2010;47(21):2982-90.		
95.	* Standring S, ed. Gray's Anatomy: The Anatomical Basis of Clinical Practice, 41e, Philadelphia: Elsevier Limited; 2016.		
96.	* Zuk PA, et al; Multilineage cells from human adipose tissue: implications for cell-based therapies. Tissue Eng., 2001;7(2): 211-28.		
97.	* Zuk PA, et al; Human adipose tissue is a source of multipotent stem cells; Mol Biol Cell, 2002;13(12):4279-95.	5/6/2021	
98.	* Mitchell JB et al; Immunophenotype of human adipose-derived cells: temporal changes in stromal-associated and stem cell-associated markers. Stem Cells, 2006;24(2):376-385.	5/6/2021	
99.	* Riordan NH et al; Non-expanded adipose stromal vascular fraction cell therapy for multiple sclerosis. J Transl Med. 2009; 7-29.	5/6/2021	
100.	* Pak et al; Current use of autologous adipose tissue-derived stromal vascular fraction cells for orthopedic applications. J Biomed Science, 2017; 24(9);1-12.		
101.	* Gimble JM, et al; Adipose-derived stem cells for regenerative medicine. Circ. Res 2007; 100:1249-1260.		
102.	* Chan TM et al; The use of ADSCs as a treatment for chronic stroke. Cell Transplant. 2014;23(4-5):541-7		
103.	* Chang, KA et al; Therapeutic Potential of Human Adipose-Derived Stem Cells in Neurological Disorders. J Pharm Sciences, Dec 2014; 126(4); 293-301		

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104.	* Xiang LB et al; Stem cell transplantation for treating spinal cord injury. A literature comparison between studies of stem cells obtained from various sources. Neural Regeneration Research, 2012;7(16), 1256-1263		
105.	* Shende P, Subedi M; Pathophysiology, mechanisms and applications of mesenchymal stem cells for the treatment of spinal cord injury. Biomedicine and Pharmacotherapy, 2017 Jul;91:693-706		
106.	* Wecht, S et al; Mesenchymal stem cells in the treatment of chronic lung disease; Respirology, 2016, 21(8),1366-1375		
107.	* Oh DK, et al; Lung regeneration therapy for chronic obstructive pulmonary disease. Tuberculosis and Respiratory Diseases Jan 2017, 80:1 (1-10) 1		
108.	* Mead B et al; Stem cell treatment of degenerative eye disease. Stem Cell Res. 2015 May;14(3):243-57		
109.	* Pak J, et al; Cartilage regeneration in human with adipose tissue-derived stem cells and adipose stromal vascular fraction cells: Updated Status. Int. J Mol. Sci. Jul 2018, 19(7): 2146.		
110.	* Nguyen A, Guo J, et al; Stromal vascular fraction: A regenerative reality? Part 1: Current concepts and review of the literature. JPRAS, Feb 2016, 69(2), 170-179, 180-8		
111.	* Gharravi, AM, Jafar A, et al; Current status of stem cell therapy and scaffolds for the treatment of diabetes mellitus. Diabetes and Metabolic Syndrome: Clinical Research and Reviews 2018 12:6 (1133-1139)		
112.	* LaPrade R, et al; AAOS Research symposium updates and consensus: biologic treatment of orthopedic injuries. J Am. Acad. of Orthop. Surg., 2016; 24: e62-e78.		
113.	* Kuriyan AE et al; Vision Loss after Intravitreal Injection of Autologous “Stem Cells” for AMD. N Engl. J Med. 2017 Mar 16;376(11):1047-1053		

Ex. No.	Description	Date Identified	Date Admitted
114.	* Saraf SS, et al. Bilateral Retinal Detachments After Intravitreal Injection of Adipose-Derived ‘Stem Cells’ in a Patient with Exudative Macular Degeneration. Ophthalmic Surg. Lasers Imaging Retina. Sep. 2017;48(9): 772-775.		
115.	* American Academy of Ophthalmology Statement on Stem Cell Therapy for Treating Eye Disease <a href="https://www.aao.org/newsroom/news-releases/detail/statement-stem-cell-therapy-treatment-eye-disease">https://www.aao.org/newsroom/news-releases/detail/statement-stem-cell-therapy-treatment-eye-disease</a>		
116.	* Stem Cell Therapy for Lung Diseases <a href="https://www.lung.org/our-initiatives/research/about-our-research/stem-cell-therapy.html">https://www.lung.org/our-initiatives/research/about-our-research/stem-cell-therapy.html</a>		
117.	<b>FDA-approved labeling for ACAM2000 – Smallpox (Vaccinia) Vaccine, Live (2018)</b>	5/4/2021 stip	5/4/2021 stip
118.	* Pak J et al; Safety reporting on implantation of autologous adipose tissue-derived stem cells with platelet-rich plasma into human articular joints. BMC, Musculoskelet Disord, 2013;14-337		
119.	* Siennicka K et al; Adipose-derived cells (stromal vascular fraction) transplanted for orthopedic or neurological purposes: are they safe enough? Stem Cell International, 2016 Article ID 5762916	5/6/2021	
120.	* Lalu MM et al; Safety of cell therapy with mesenchymal stromal cells (SafeCell): a systematic review and meta-analysis of clinical trials. PLoS ONE 2012;7 (10): e47559	5/6/2021	
121.	* Rodriguez JP et al; Autologous stromal vascular fraction therapy for rheumatoid arthritis: rationale and clinical safety. Int. Arch Med, 2012, 5:5		
122.	* Jung JW et al; Familial occurrence of pulmonary embolism after intravenous adipose tissue-derived stem cell therapy. Yonsei Med J, 2013;54: 1293-96.		

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123.	* Tatsumi et al; Tissue factor triggers procoagulation in transplanted mesenchymal stem cells leading to thromboembolism. Biomedical and Biophysical Research Communications 2013, 431; 203-209		
124.	* Staff N et al; Safety of intrathecal autologous adipose-derived mesenchymal stromal cells in patients with ALS. Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration; 2016; Neurology 2016: 87: 2230-2234	5/6/2021	
125.	* Hur, JW et al; Intrathecal transplantation of autologous adipose-derived mesenchymal stem cells for treating spinal cord injury: A human trial. Journal of Spinal Cord Medicine; SN 1079-0268, 2016 (39) 6:655-664		
126.	* Ratcliffe E, Thomas RJ, Williams DJ. Current understanding and challenges in bioprocessing of stem cell-based therapies for regenerative medicine. British Medical Bulletin. 2011;100(1):137-55.		
127.	* Lin-Gibson S, et al; Points to Consider for Cell Manufacturing Equipment and Components. Cell Gene Therapy Insights. 2017; 3(10), 793-805.		
128.	* Alberts B, Johnson A, Lewis J, et al. Molecular Biology of the Cell. 4th edition. New York: Garland Science; 2002. The Extracellular Matrix of Animals. Available from: <a href="http://www.ncbi.nlm.nih.gov/books/NBK26810/">http://www.ncbi.nlm.nih.gov/books/NBK26810/</a>		
129.	* Bjorntorp P, Martinsson A. The composition of human subcutaneous adipose tissue in relation to its morphology. Acta Med. Scand., 179 (4) (1966), pp. 475-481.		
130.	* Viot P, Hydrostatic compression on polypropylene foam. International Journal of Impact Engineering. 2009;36(7):975-89.		
131.	* Image from <a href="https://www.foambyemail.com/GR-_BLACK/gym-rubber-black.html">https://www.foambyemail.com/GR-_BLACK/gym-rubber-black.html</a>		

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132.	* Greenwood MRC, Johnson PR. Histology, Cell and Tissue Biology. 5th edition. Macmillan; 1983. The adipose tissue. pp. 178-199.		
133.	* Ford AL, Foulcher E, Goodsall AL, Sedgwick JD. Tissue digestion with dispase substantially reduces lymphocyte and macrophage cell-surface antigen expression. Journal of Immunological Methods. 1996;194(1):71-5.	5/6/2021	
134.	* Autengruber A, Gereke M, Hansen G, Hennig C, Bruder D. Impact of enzymatic tissue disintegration on the level of surface molecule expression and immune cell function. European journal of microbiology & immunology. 2012;2(2):112-20.	5/7/2021	
135.	* Golunova A, Jaroš J, Sedláková V, Kotelnikov I, Kotek J, Hlídková H, et al. N - (2-Hydroxypropyl) Methacrylamide Based Cryogels – Synthesis and Biomimetic Modification for Stem Cell Applications 2015. S19-S27.	5/6/2021	
136.	* NIH Stem Cell Information Home Page. In Stem Cell Information [World Wide Web site]. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2016 [cited February 7, 2019] Available at <a href="https://stemcells.nih.gov/info/basics/4.htm">https://stemcells.nih.gov/info/basics/4.htm</a>		
137.	* Kilinc MO, Santidrian A, Minev I, Toth R, Draganov D, Nguyen D, Lander E, Berman M, Minev B, and Szalay AA. The ratio of ADSCs to HSC-progenitors in adipose tissue derived SVF may provide the key to predict the outcome of stem-cell therapy. Clinical and Translational Medicine. 2018;7(1):5.	5/6/2021	
138.	* Alberts, B, et. al, editors. Molecular Biology of the Cell (Sixth Edition). New York: Garland Science, 2008.		

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139.	* Taghizadeh RR, Cetrulo KJ, Cetrulo CL. Collagenase Impacts the Quantity and Quality of Native Mesenchymal Stem/Stromal Cells Derived during Processing of Umbilical Cord Tissue. Cell Transplant. 2018 Jan;27(1):181-193. doi: 10.1177/0963689717744787.	5/6/2021	
140.	* Bianca Vezzani, et al. Higher Pericyte Content and Secretory Activity of Microfragmented Human Adipose Tissue Compared to Enzymatically Derived Stromal Vascular Fraction. STEM CELLS TRANSLATIONAL MEDICINE 2018; 7: 876–886.	5/6/2021	
141.	* M. Garcia-Contreras et al., Differences in Exosome Content of Human Adipose Tissue Processed by Non-Enzymatic and Enzymatic Methods, CellR4, 3 (1) (2015).	5/6/2021	
142.	* Susanne C van den Brink, et al. Single-cell sequencing reveals dissociation-induced gene expression in tissue subpopulations. Nature Methods volume 14, pages935–936(2017).		
143.	* Viola Maria Schmidt, Vladimir Isachenko, et al. Comparison of the enzymatic efficiency of Liberase TM and tumor dissociation enzyme: effect on the viability of cells digested from fresh and cryopreserved human ovarian cortex. Reprod Biol Endocrinol. 2018; 16: 57. Published online 2018 Jun 2. doi: 10.1186/s12958-018-0374-6	5/6/2021	
144.	* Valerie Y. Soldatow et al., In vitro models for liver toxicity testing, Toxicol Res (Camb). 2013 January 1; 2(1): 23–39.	5/6/2021	
145.	* Soo-Hun Kim et al., Extracellular matrix and cell signalling: the dynamic cooperation of integrin, proteoglycan and growth factor receptor, J Endocrinol. 209(2):139-51 (2011).	5/6/2021	
146.	* Pham, Phuc Van. Clinical Trials for Stem Cell Transplantation: When are they needed? Stem Cell Research and Therapy (2016) 7:65	5/6/2021	



Ex. No.	Description	Date Identified	Date Admitted
147.	* Benoit, E, et al. Safety and Efficacy of Autologous Cell Therapy in Critical Limb Ischemia: A Systematic Review. Cell Transplantation, Vol 22, 545-562, 2013		
148.	* Sun X, et al. Meta-analysis on autologous stem cell transplantation in the treatment of limb ischemic. Int. J. Clin. Exp. Med., 8(6), 2015		
149.	* Ma, XR, et al. Transplantation of Autologous Mesenchymal Stem Cells for End-Stage Liver Cirrhosis: A Meta-analysis based on Seven Controlled Trials. Hindawi Publishing Corporation, Gastroenterology Res. Pract., 2015 id908275		
150.	* Bhansali et al. Efficacy and safety of autologous bone marrow-derived stem cell transplantation in patients with type 2 diabetes mellitus: a randomized placebo-controlled study. Cell Transplant. 2014;23(9):1075-85.		
151.	* Michalek J, et al. Stromal Vascular Fraction cells of adipose and connective tissue in patients with osteoarthritis: A case control prospective multi-centric non-randomized study. Glob. Surg. Vol 3(3):1-9, 2017		
152.	* Culme-Seymour E, et al. A decade of cell therapy clinical trials (2000-2010), Regen Med 7(4), 455-462, 2012		
153.	* Mason C and Manzotti E, Regenerative medicine cell therapies: numbers of units manufactured, and patients treated between 1988 and 2010. Regen. Med. 5(3), 307-313, 2010		
154.	<b>Protocol - Clinical Efficacy of Autologous Stromal Vascular Fraction SVF or Autologous Laboratory Expanded Mesenchymal Stem Cells (MSCs) for Acute COVID-19 Infection</b>	5/4/2021 stip	5/4/2021 stip
155.	COI Patient File (N.K.) 2017 EIR (Rancho Mirage) Ex. WFL54		
156.	Listing of Cells On Ice (COI) Affiliates 2017 EIR (Rancho Mirage) Ex. WFL48	5/11/2021	5/11/2021

Ex. No.	Description	Date Identified	Date Admitted
157.	Patient S101-032 File (L.H.) <i>2017 EIR (Rancho Mirage) Ex. CJ45</i>		
158.	COI Expanded Cell, Transport Patients List <i>2017 EIR (Rancho Mirage) Ex. CJ18</i>		
159.	<b>Sterile Technique document</b> <i>2017 EIR (Beverly Hills) Ex. DC11</i>	5/4/2021 stip	5/4/2021 stip
160.	Quality Procedures document <i>2017 EIR (Beverly Hills) Ex. MF22</i>	5/5/2021	5/5/2021
161.	<b>Protocol - Clinical Intervention Study: Efficacy of Adipose Derived SVF for Inflammatory and Degenerative Knee Conditions</b> <i>2017 EIR (Beverly Hills) Ex. MF8</i>	5/4/2021 stip	5/4/2021 stip
162.	Images of Adipose Tissue and Adipose Tissue-derived Stem Cells		
163.	Defendants' Written Responses to Knoepfler Lab Stem Cell Blog's 2013 Written Interview Questions		
163a	Metadata for Defendants' Written Responses to Knoepfler Lab Stem Cell Blog's 2013 Interview Questions		
164.	Defendants' Written Responses to Knoepfler Lab Stem Cell Blog's 2017 Interview Questions		
164a	Email from Knoepfler to Berman and Lander 1-26-17		
164b	Email from Berman and Lander to Knoepfler 1-26-17		
164c	Email from Knoepfler to Berman and Lander 1-26-17		
164d	Email from Berman and Lander to Knoepfler 1-27-17		
164e	Email from Knoepfler to Berman and Lander 1-27-17		
164f	Email from Berman and Lander to Knoepfler 1-28-17		
164g	Email from Knoepfler to Berman and Lander 1-30-17		
165.	Defendants' Additional Emails re: Knoepfler Lab Stem Cell Blog's 2017 Interview Questions		
165a	Email from Knoepfler to Berman and Lander 1-30-17		
165b	Email from Berman and Lander to Knoepfler 1-30-17		

Ex. No.	Description	Date Identified	Date Admitted
165c	Email from Knoepfler to Berman and Lander 1-30-17		
165d	Email from Berman and Lander to Knoepfler 1-30-17		
166.	<b>Defendants' Verification of Interrogatory Responses</b>	5/4/2021 stip	5/4/2021 stip
167.	Cells of Ice (COI) Brochure <i>2017 EIR (Rancho Mirage) Ex. CJ17</i>	5/11/2021	5/11/2021
168.	International Cell Surgical Society (ICSS) IRB Brochure <i>2017 EIR (Rancho Mirage) Ex. CJ4</i>	5/11/2021	5/11/2021
169.	ICSS IRB Member Directory <i>2017 EIR (Rancho Mirage) Ex. CJ5</i>	5/11/2021	5/11/2021
170.	<b>ICSS IRB Approval Letters</b> <i>2017 EIR (Rancho Mirage) Ex. WFL29</i>	5/4/2021 stip	5/4/2021 stip
171.	Patient S101-035 File (G.K.) <i>2017 EIR (Rancho Mirage) Ex. CJ48</i>		
172.	Transportation Log <i>2017 EIR (Rancho Mirage) Ex. CJ60</i>	5/11/2021	5/11/2021
173.	American CryoStem Packing Slips <i>2017 EIR (Rancho Mirage) Ex. CJ19</i>	5/11/2021	5/11/2021
174.	CSN Affiliates Listing <i>2017 EIR (Rancho Mirage) Ex. WFL2</i>	5/11/2021	5/11/2021
175.	FDA Disapproval Letter for Defendants' Investigational Device (IDE) Application <i>2017 EIR (Rancho Mirage) Ex. CJ52</i>	5/11/2021	5/11/2021
176.	<b>COI Transportation Protocol</b> <i>2017 EIR (Rancho Mirage) Ex. CJ22</i>	5/4/2021 stip	5/4/2021 stip
177.	American CryoStem Certificate of Analysis (COA) for expanded cells <i>2017 EIR (Rancho Mirage) Ex. CJ21</i>		
178.	FEDEX Shipments – Roche <i>2017 EIR (Rancho Mirage) Ex. CJ58</i>	5/11/2021	5/11/2021
179.	CSN IRB SAEs for Various Patients <i>2017 EIR (Rancho Mirage) Ex. WFL28</i>		

Ex. No.	Description	Date Identified	Date Admitted
180.	Photograph of CSN shipping office <i>2017 EIR (Rancho Mirage) Ex. WFL41</i>		
181.	<b>Photograph of employee at manufacturing table</b> <i>2017 EIR (Rancho Mirage) Ex. WFL33</i>	5/4/2021 stip	5/4/2021 stip
182.	CSN Adverse Events <i>2017 EIR (Rancho Mirage) Ex. WFL9</i>		
183.	<b>Lander Affidavit, dated July 26, 2017 (5 pages)</b> <i>2017 EIR (Rancho Mirage) Attachment - WFL</i>	5/4/2021 stip	5/4/2021 stip
184.	Carolyn Yong, Ph.D., <i>Curriculum Vitae</i>	5/7/2021	5/7/2021
185.	Larissa Lapteva, M.D., <i>Curriculum Vitae</i>	5/5/2021	5/5/2021
186.	Doran L. Fink, M.D., Ph.D., <i>Curriculum Vitae</i>		
187.	Randa Melhem, Ph.D., <i>Curriculum Vitae</i>		
188.	Food & Drug Admin., <i>Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception</i> , Draft Guidance for Industry (Oct. 2014)		
189.	<b>FDA-approved labeling for ACAM2000 – Smallpox (Vaccinia) Vaccine, Live (2009)</b>	5/4/2021 stip	5/4/2021 stip
190.	CSCTC Business History Records <i>2017 EIR (Beverly Hills) Ex. MF1</i>	5/5/2021	5/5/2021
191.	COI Business History Records <i>2017 EIR (Beverly Hills) Ex. MF9</i>	5/5/2021	5/5/2021
192.	List of deployment doctors and imaging centers <i>2017 EIR (Beverly Hills) Ex. MF14</i>		

## II. DEFENDANTS' EXHIBITS

Ex. No.	Description	Date Identified	Date Admitted
300.	Mark Berman, M.D., F.A.C.S., <i>Curriculum Vitae</i> (Nov. 2018)	5/11/2021	5/11/2021
301.	Lola Reid, Ph.D., <i>Curriculum Vitae</i> (2019)	5/12/2021	5/12/2021

Ex. No.	Description	Date Identified	Date Admitted
302.	Accreditation Association for Ambulatory Healthcare: Accreditation of Mark Berman, M.D., F.A.C.S. (Mar. 2018)	5/11/2021	5/11/2021
303.	<i>User Manual: CSN-Time Machine ® Method for Preparing SVF</i> (July 2017)	5/4/2021 stip	5/4/2021 stip
304.	<i>Detailed Operating Procedures for the CSN Time Machine® System</i> [CALSTEM000001-000011]	5/4/2021 stip	5/4/2021 stip
305.	<i>Standard Operating Procedures of Cell Surgical Network</i> [CALSTEM000012-000029]	5/4/2021 stip	5/4/2021 stip
306.	<i>Infection Control in the OR</i> [CALSTEM000030-000031]	5/4/2021 stip	5/4/2021 stip
307.	<i>Outgoing Transportation of Cells</i> [CALSTEM00032-00035] (Mar. 25, 2015)	5/4/2021 stip	5/4/2021 stip
308.	<i>Aseptic Technique</i> [CALSTEM000036-000037]	5/4/2021 stip	5/4/2021 stip
309.	<i>Autoclave Spore Check</i> [CALSTEM000038]	5/4/2021 stip	5/4/2021 stip
310.	<i>Handwashing</i> [CALSTEM000039]	5/4/2021 stip	5/4/2021 stip
311.	<i>Drapes and Draping</i> [CALSTEM000040]	5/4/2021 stip	5/4/2021 stip
312.	<i>Gloving Methods/Infection Control</i> [CALSTEM000041]	5/4/2021 stip	5/4/2021 stip
313.	<i>Mask Recommendations for all Stromal Vascular Fraction (SVF) Procedures</i> [CALSTEM000042]	5/4/2021 stip	5/4/2021 stip
314.	<i>Terminal Cleaning of the Operating Room</i> [CALSTEM000043]	5/4/2021 stip	5/4/2021 stip
315.	<i>Cleaning O.R. Between Cases</i> [CALSTEM000044]	5/4/2021 stip	5/4/2021 stip
316.	<i>Cell Surgical Network, Surgical Production of Stromal Vascular Fraction (SVF)</i> [CALSTEM000045-CALSTEM000131]	5/4/2021 stip	5/4/2021 stip

<b>Ex. No.</b>	<b>Description</b>	<b>Date Identified</b>	<b>Date Admitted</b>
317.	<b>Cell Surgical Network, Instructional Video of SVF Surgical Procedure, Pt. 1 [CALSTEM000132]</b>	5/4/2021 stip	5/4/2021 stip
318.	<b>Cell Surgical Network, Instructional Video of SVF Surgical Procedure, Pt. 2 [CALSTEM000133]</b>	5/4/2021 stip	5/4/2021 stip
319.	<b>Cell Surgical Network, Instructional Video of SVF Surgical Procedure, Pt. 3 [CALSTEM000134]</b>	5/4/2021 stip	5/4/2021 stip
320.	<b>Cell Surgical Network, Instructional Video of SVF Surgical Procedure, Pt. 4 [CALSTEM000135]</b>	5/4/2021 stip	5/4/2021 stip
321.	<b>Cell Surgical Network, Instructional Video of SVF Surgical Procedure, Pt. 5 [CALSTEM000136]</b>	5/4/2021 stip	5/4/2021 stip
322.	<b>Cell Surgical Network, Instructional Video of SVF Surgical Procedure, Pt. 6 [CALSTEM000137]</b>	5/4/2021 stip	5/4/2021 stip
323.	<b>Investigational Device Exemption (New Indication for Marketed Device), CSN-Time Machine® System – Knee Osteoarthritis Study (Nov. 30, 2017) [CALSTEM000292-000606]</b>	5/4/2021 stip	5/4/2021 stip
324.	Individual Patient Expanded Access IND Application (Patient CT) (Nov. 9, 2017) [CALSTEM002500-002502]		
325.	Individual Patient Expanded Access IND Application (Patient WD) (Feb. 2, 2018) [CALSTEM002378-002379]		
326.	Individual Patient Expanded Access IND Application (Patient JD) (Feb. 2, 2018) [CALSTEM002306-002307]		
327.	Additional Clinical History (Patient JD) (Feb. 2, 2018) [CALSTEM002371-002377]		
328.	Individual Patient Expanded Access IND Application (Patient JS) (Feb. 2, 2018) [CALSTEM002308-002309]		
329.	<i>Additional</i> Clinical History (Patient JS) (Feb. 2, 2018) [CALSTEM002338-002346]		

Ex. No.	Description	Date Identified	Date Admitted
330.	Individual Patient Expanded Access IND Application (Patient GV) (Feb. 2, 2018) [CALSTEM002310-002311]		
331.	Additional Clinical History (Patient GV) (Feb. 2, 2018) [CALSTEM002329-002335]		
332.	Individual Patient Expanded Access IND Application (Patient CS) (Feb. 2, 2018) [CALSTEM002314-002315]		
333.	<i>Additional</i> Clinical History (Patient CS) (Feb. 2, 2018) [CALSTEM002292-002298]		
334.	Individual Patient Expanded Access IND Application (Patient AS) (Feb. 2, 2018) [CALSTEM002316-002317]		
335.	Additional Clinical History ( <i>Patient</i> AS) (Feb. 2, 2018) [CALSTEM002285-002291]		
336.	Individual Patient Expanded Access IND Application (Patient VM) (Feb. 21, 2018) [CALSTEM002312-002313]		
337.	Additional Clinical <i>History</i> (Patient VM) (Feb. 21, 2018) [CALSTEM002347-002352]		
338.	Individual Patient Expanded Access IND Application (Patient JED) (Feb. 14, 2018) [CALSTEM002367-002368]		
339.	Additional Clinical History (Patient JED) (Feb. 14, 2018) [CALSTEM002353-002359]		
340.	Individual Patient Expanded Access IND Application (Patient DS) (Feb. 14, 2018) [CALSTEM002369-002370]		
341.	Additional Clinical History (Patient DS) (Feb. 14, 2018) [CALSTEM002299-002305]		
342.	Individual Patient Expanded Access IND Application (Patient WM) (Feb. 21, 2018) [CALSTEM002318-002319]		



<b>Ex. No.</b>	<b>Description</b>	<b>Date Identified</b>	<b>Date Admitted</b>
343.	Additional Clinical History (Patient WM) (Feb. 21, 2018) [CALSTEM002322-002328]		
344.	Individual Patient Expanded Access IND Application (Patient BM) Feb. 21, 2018) [CALSTEM002320-002321]		
345.	Additional Clinical History (Patient BM) (Feb. 21, 2018) [CALSTEM002278-002284]		
346.	Individual Patient Expanded Access IND Application (Patient LD) (Feb. 21, 2018) [CALSTEM002336-002337]		
347.	Additional Clinical History (Patient LD) (Feb. 21, 2018) [CALSTEM002360-002366]		
348.	Autengruber A et al. Impact of enzymatic tissue disintegration on the level of surface molecule expression and immune cell function. Eur J Microbiol and Immunol, 2, pp. 112-120 (2012)		
349.	Bellows CF et al. Circulation of progenitor cells in obese and lean colorectal cancer patients. Cancer Epidemiol Biomarkers Prev. 2011; 20:2461-2468		
350.	Bellows CF et al. Influence of BMI on level of circulating progenitor cells. Obesity. 2011; 19:1722-1726		
351.	Berman M. & Lander E. A Prospective Safety Study of Autologous Adipose-Derived Stromal Vascular Fraction Using a Specialized Surgical Processing System. American J of Cosmetic Surg. 2017:1–14, at 8-9	5/6/2021	
352.	Berman M. et al. Prospective Study of Autologous Adipose Derived Stromal Vascular Fraction Containing Stem Cells for the Treatment of Knee Osteoarthritis Int. J. Stem Cell Res. Ther. 2019, 6:064		
353.	Carvalho P. et al, Xenofree Enzymatic Products for the Isolation of Human Adipose-Derived Stromal/Stem Cells Tissue Eng. 19:6 (2013)	5/6/2021	

Ex. No.	Description	Date Identified	Date Admitted
354.	Chang H et al. Safety of adipose-derived stem cells and collagenase in fat tissue preparation. Aesthetic Plast. Surg. 2013 Aug; 37(4):802-8		
355.	Coelho M et al. <i>Biochemistry of adipose tissue: an endocrine organ</i> . Arch Med Sci. 2013; 9, 2: 191-200, at 191		
356.	Di Vitantonio H. et al. Dural repair using autologous fat: Our experience and review of the literature Surg. Neurol. Int. 2016:6		
357.	Duma C. et al. Human intracerebroventricular (ICV) injection of autologous, non-engineered, adipose-derived stromal vascular fraction (ADSVF) for neurodegenerative disorders, results of 3-year phase 1 study of 113 injections in 31 patients, Molecular Biology Reports 2019.	5/6/2021	
358.	Gimble JM et al. Adipose-derived stem cells for regenerative medicine. Circ Res. 2007; 100:1249-1260		
359.	Hardy WR et al. Transcriptional networks in single perivascular cells sorted from human adipose tissue reveal a hierarchy of mesenchymal stem cells. Stem Cells. 2017 May; 35(5):1273-1289		
360.	Hematti P & Keating A (2013) Mesenchymal stromal cells in regenerative medicine: a perspective. Mesenchymal stromal cells: biology and clinical applications. Human Press, New York		
361.	Hindle P et al. The infrapatellar fat pad as a source of perivascular stem cells with increased chondrogenic potential for regenerative medicine. Stem Cells Transl Med. 2017 Jan; 6(1):77-87		
362.	Kershaw EE & Flier JS. <i>Adipose tissue as an endocrine organ</i> . J Clin Endocrinol Metab. 2004 Jun; 89(6):2548-56		

Ex. No.	Description	Date Identified	Date Admitted
363.	Kilinc MO et al. The ratio of ADSCs to HSC-progenitors in adipose tissue derived SVF may provide the key to predict the outcome of stem-cell therapy. Clin Transl Med. 2018, 7:5	5/6/2021	
364.	Kim EJ et al. Platelet-derived growth factor receptorpositive pericytic cells of white adipose tissue from critical limb ischemia patients display mesenchymal stem cell-like properties. Clin Orthop Surg. 2017 Jun; 9(2):239-248		
365.	Kokai LE et al. (2014) Adipose stem cells: biology and clinical applications for tissue repair and regeneration. Transl Res 63:399–408		
366.	Lander E. et al. <i>Safety of stromal vascular fraction cells applications in chronic pain</i> Techniques in Reg. Anesthesia & Pain Management 2015:10-13.	5/6/2021	
367.	Lander E. et al. Stromal Vascular Fraction Combined with Shock Wave for the Treatment of Peyronie's Disease Plastic & Reconstructive Surgery - Global Open 2016:1.		
368.	Lander E. & Berman M. Autologous Stromal Vascular Fraction Containing Stem Cells Combined with Low Intensity Shock Wave for the Treatment of Human Erectile Dysfunction. J. of Stem Cell Res. & Ther. 2018 8:9		
369.	Lander E. et al. Autologous Stromal Vascular Fraction: A New Era of Personal Cell Therapy, J. Stem Cell Res. Dev. 2018:4:011		
370.	Lander E. et al. Personal cell therapy for interstitial cystitis with autologous stromal vascular fraction stem cells, Ther. Avd. Urol. 2019, 11:1-9	5/11/2021	
371.	Liebermann-Meffert D. The greater omentum: anatomy, embryology, and surgical applications. Surg Clin North Am. 2000 Feb; 80(1):275-93		

Ex. No.	Description	Date Identified	Date Admitted
372.	Lockhart, R.A. et al. Tissue Dissociation Enzymes for Adipose Stromal Vascular Fraction Cell Isolation: A Review, J. of Stem Cell Res. & Therapy, 5:12 at 4 (2015)		
373.	Merrick, D. et al. Identification of a mesenchymal progenitor cell hierarchy in adipose tissue, Science 2019:364		
374.	Michalek, J. et al. Stromal vascular fraction cells of adipose and connective tissue in patients with osteoarthritis: A case control prospective multi-centric non-randomized study, Global Surg. 2017 3(3):1-9.		
375.	Pham P Clinical trials for stem cell transplantation: when are they needed? Stem Cell Research & Therapy (2016) 7:65		
376.	Rodriguez, R. Arguments for a Different Regulatory Categorization and Framework for Stromal Vascular Fraction Stem Cells and Dev. 2020.		
377.	Sakaguchi Y et al. Suspended cells from trabecular bone by collagenase digestion become virtually identical to mesenchymal stem cells obtained from marrow aspirates. Blood J Org., 2004 104:2728-2735		
378.	<b>FDA, Proposed Approach to Regulation of Cellular and Tissue-Based Products (Feb. 1997), available at <a href="https://www.fda.gov/media/70704/download">https://www.fda.gov/media/70704/download</a></b>	5/4/2021 stip	5/4/2021 stip
379.	[Exhibit withdrawn]		
380.	<b><i>ACAM2000 (Smallpox Vaccine) Questions and Answers (Mar. 23, 2018), available at <a href="https://www.fda.gov/vaccines-blood-biologics/vaccines/acam2000-smallpox-vaccine-questions-and-answers">https://www.fda.gov/vaccines-blood-biologics/vaccines/acam2000-smallpox-vaccine-questions-and-answers</a> (Mar. 2018)</i></b>	5/4/2021 stip	5/4/2021 stip
381.	[Exhibit withdrawn]		
382.	<b>Press Release, Food &amp; Drug Administration FDA acts to remove unproven, potentially harmful treatment used in “stem cell” centers targeting vulnerable patients (Aug. 28, 2017)</b>	5/4/2021 stip	5/4/2021 stip

Ex. No.	Description	Date Identified	Date Admitted
383.	<b><i>USA v. Five Articles of Drug, ACAM2000, Vaccinia Vaccine, Live</i></b> , No. SACV17-01449- JVS (KESx), 2018 WL 6318834, at *2 (C.D. Cal. Jan. 30, 2018)	5/4/2021 stip	5/4/2021 stip
384.	<b>FDA, 510(k) Premarket Notification for Lipokit with Disposable 55CC AFT Syringe, Model ZLK-100</b> (last accessed Apr. 18, 2020), <i>available at</i> <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K083455">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K083455</a>	5/4/2021 stip	5/4/2021 stip
385.	<b>Letter from FDA to Medi-Khan USA, Inc. re: Clearance of K121703, Lipokit with disposable 50cc AFT Syringe</b> (Dec. 7, 2012), <i>available at</i> <a href="https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121703.pdf">https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121703.pdf</a>	5/4/2021 stip	5/4/2021 stip
386.	<b>FDA, Establishment Registration and Device Listing: Cellibator BREATHE; Cellibrator GT</b> (last accessed pr. 18, 2020), <i>available at</i> <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=478559&amp;lpcd=NNL">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=478559&amp;lpcd=NNL</a>	5/4/2021 stip	5/4/2021 stip
387.	<b>Baxter, Label for Lactated Ringer's and Dextrose 5% In Plastic Container</b> (Oct. 2019)	5/4/2021 stip	5/4/2021 stip
388.	<b>Approval History for Baxter Lactated Ringer's and Dextrose 5% In Plastic Container 500</b> , <i>available at</i> <a href="https://www.accessdata.fda.gov/scripts/cder/daf/">https://www.accessdata.fda.gov/scripts/cder/daf/</a> (search Drug Name, Active Ingredient, or Application Number field for "016679") (last accessed Apr. 18, 2020)	5/4/2021 stip	5/4/2021 stip
389.	<b>B. Braun, Label for Lactated Ringer's and Dextrose 5% In Plastic Container</b> (Feb. 2013)	5/4/2021 stip	5/4/2021 stip
390.	<b>Approval History for B. Braun Lactated Ringer's and Dextrose 5% In Plastic Container 500</b> , <i>available at</i> <a href="https://www.accessdata.fda.gov/scripts/cder/daf/">https://www.accessdata.fda.gov/scripts/cder/daf/</a> (search Drug Name, Active Ingredient, or Application Number field for "019634") (last accessed Apr. 18, 2020)	5/4/2021 stip	5/4/2021 stip

Ex. No.	Description	Date Identified	Date Admitted
391.	<b>Baxter, Label for 0.9% Sodium Chloride Injection, USP, 100 mL Label (May 2019)</b>	5/4/2021 stip	5/4/2021 stip
392.	<b>Approval History for Baxter 0.9% Sodium Chloride Injection, USP, 100 mL, available at <a href="https://www.accessdata.fda.gov/scripts/cder/daf/">https://www.accessdata.fda.gov/scripts/cder/daf/</a> (search Drug Name, Active Ingredient, or Application Number field for “016677”) (last accessed Apr. 18, 2020)</b>	5/4/2021 stip	5/4/2021 stip
393.	<b>Hospira (n/k/a/ Pfizer), Label for 0.9% Sodium Chloride Injection, USP, 100 mL Label (May 2014)</b>	5/4/2021 stip	5/4/2021 stip
394.	<b>Approval History for Hospira (n/k/a Pfizer) 0.9% Sodium Chloride Injection, USP, 100 mL, available at <a href="https://www.accessdata.fda.gov/scripts/cder/daf/">https://www.accessdata.fda.gov/scripts/cder/daf/</a> (search Drug Name, Active Ingredient, or Application Number field for “019465”) (last accessed Apr. 18, 2020)</b>	5/4/2021 stip	5/4/2021 stip
395.	<b>Roche, <i>Liberase MNP-S GMP Grade Product Information</i> (last accessed Apr. 18, 2020), available at <a href="https://custombiotech.roche.com/home/Product_Detail/s/3_5_3_3_11_10.html">https://custombiotech.roche.com/home/Product_Detail/s/3_5_3_3_11_10.html</a></b>	5/4/2021 stip	5/4/2021 stip
396.	<b>Roche Life Science, Diagnostic Operations Penzberg-Quality Control Specifications CSN-TMAX™ [CALSTEM000512]</b>	5/4/2021 stip	5/4/2021 stip
397.	<b>Roche Life Science, Diagnostic Operations Penzberg-Quality Control Specifications Liberase MNP-S [CALSTEM000513]</b>	5/4/2021 stip	5/4/2021 stip
398.	<b>Roche Diagnostics GmbH, Certificate of Analysis (July 2014) [FDA008382]</b>	5/4/2021 stip	5/4/2021 stip
399.	<b>Roche Diagnostics GmbH, Certificate of Analysis (July 2014) [FDA008383]</b>	5/4/2021 stip	5/4/2021 stip
400.	<b>Roche Diagnostics GmbH, Certificate of Analysis (Dec. 2014) [FDA008384]</b>	5/4/2021 stip	5/4/2021 stip
401.	<b>Roche Diagnostics GmbH, Certificate of Analysis (Nov. 2014) [CALSTEM000514]</b>	5/4/2021 stip	5/4/2021 stip



<b>Ex. No.</b>	<b>Description</b>	<b>Date Identified</b>	<b>Date Admitted</b>
402.	<b>Roche Diagnostics GmbH, Letter of Notification re Lot 111 564 00 [CALSTEM000515-000517]</b>	5/4/2021 stip	5/4/2021 stip
403.	<b>Roche Diagnostics GmbH, <i>Certificate of Origin for Liberase MNP-S 5mg GMP</i> (May 18, 2015) [CALSTEM000511]</b>	5/4/2021 stip	5/4/2021 stip
404.	<b>Roche Diagnostics GmbH, Quality Control Statement for Collagenase I, <i>Roche Diagnostics ID 05172969001</i> (June 8, 2015) [CALSTEM000508]</b>	5/4/2021 stip	5/4/2021 stip
405.	<b>Roche Diagnostics GmbH, Quality Control Statement for Collagenase II, <i>Roche Diagnostics ID 05172942001</i> (June 8, 2015) [CALSTEM000509]</b>	5/4/2021 stip	5/4/2021 stip
406.	<b>Roche Diagnostics GmbH, Quality Control Statement for Thermolysin, <i>Roche Diagnostics ID 05206049001</i> (June 8, 2015) [CALSTEM000510]</b>	5/4/2021 stip	5/4/2021 stip
407.	<b>Roche Diagnostics GmbH, Certificate of Analysis (Jan. 2016) [FDA008135]</b>	5/4/2021 stip	5/4/2021 stip
408.	<b>Roche Diagnostics GmbH, Certificate of Analysis (May 2016) [FDA008381]</b>	5/4/2021 stip	5/4/2021 stip
409.	<b>Roche Diagnostics GmbH, Certificate of Analysis (Nov. 2016) [FDA008026-008027]</b>	5/4/2021 stip	5/4/2021 stip
410.	<b>Letter from Roche Diagnostics GmbH to Mark Berman, MD, FDA Submission (March 27, 2017) [CALSTEM000506-000507]</b>	5/4/2021 stip	5/4/2021 stip
411.	<b>Patient Records (JZ) [FDA007660-007735]</b>	5/4/2021 stip	5/4/2021 stip
412.	<b>Adipose SVF Cultures Test Results [FDA008385]</b>	5/4/2021 stip	5/4/2021 stip
413.	<b>Laboratory Medicine Consultants, Inc., Test Results (IA) (Aug.11, 2014) [FDA008386]</b>	5/4/2021 stip	5/4/2021 stip
414.	<b>Laboratory Medicine Consultants, Inc., Test Results (JH) (Aug. 11, 2014) [FDA008387]</b>	5/4/2021 stip	5/4/2021 stip
415.	<b>Laboratory Medicine Consultants, Inc., Test Results (JM) (Aug. 6, 2014) [FDA008388]</b>	5/4/2021 stip	5/4/2021 stip
416.	<b>Laboratory Medicine Consultants, Inc., Test Results (KY) (Aug. 4, 2014) [FDA008389]</b>	5/4/2021 stip	5/4/2021 stip



<b>Ex. No.</b>	<b>Description</b>	<b>Date Identified</b>	<b>Date Admitted</b>
417.	<b>Laboratory Medicine Consultants, Inc., Test Results (IG) (Aug. 4, 2014) [FDA008390]</b>	5/4/2021 stip	5/4/2021 stip
418.	<b>Laboratory Medicine Consultants, Inc., Test Results (BP) (Aug. 11, 2014) [FDA008391]</b>	5/4/2021 stip	5/4/2021 stip
419.	<b>Laboratory Medicine Consultants, Inc., Test Results (LS) (Aug. 20, 2014) [FDA008392]</b>	5/4/2021 stip	5/4/2021 stip
420.	<b>Laboratory Medicine Consultants, Inc., Test Results (WO) (Sept. 8, 2014) [FDA008393]</b>	5/4/2021 stip	5/4/2021 stip
421.	<b>Laboratory Medicine Consultants, Inc., Test Results (FR) (Sept. 8, 2014) [FDA008394]</b>	5/4/2021 stip	5/4/2021 stip
422.	<b>Laboratory Medicine Consultants, Inc., Test Results (VT) (Sept. 6, 2014) [FDA008395]</b>	5/4/2021 stip	5/4/2021 stip
423.	<b>Laboratory Medicine Consultants, Inc., Test Results (BH) (Sept. 16, 2014) [FDA008396]</b>	5/4/2021 stip	5/4/2021 stip
424.	<b>Laboratory Medicine Consultants, Inc., Test Results (KC) (Sept. 15, 2014) [FDA008397]</b>	5/4/2021 stip	5/4/2021 stip
425.	Expert Report of Lola Reid, Ph.D.	5/12/2021	
426.	Greve, B. et al The Impact of Erythrocyte Lysing Procedures on the Recovery of Hematopoietic Progenitor Cells in Fly Cytometric Analysis, Stem Cells 2006;24:793-799		
427.	Burrow, K. et al. Human Adipose-Derived Cells Exhibit Enhanced Proliferative Capacity and Retain Multipotency Longer than Donor-Matched Bone Marrow Mesenchymal Stem Cells during Expansion in Vitro, Hindawi 2017		
428.	<b>International Cell Surgical Society SVF Vaccinia Consent Form</b>	5/4/2021 stip	5/4/2021 stip
429.	<b>International Cell Surgical Society Informed Consent Form</b>	5/4/2021 stip	5/4/2021 stip
430.	<b>California Stem Cell Treatment Center, Inc. and Cell Surgical Network Affiliate Credentialing Application</b>	5/4/2021 stip	5/4/2021 stip

Ex. No.	Description	Date Identified	Date Admitted
431.	<b>Cell Surgical Network Domestic Affiliate Agreement</b>	5/4/2021 stip	5/4/2021 stip
432.	<b>Cells on Ice, Inc. Client Agreement</b>	5/4/2021 stip	5/4/2021 stip
433.	Baker, M. Adult Cells Reprogrammed to Pluripotency, Without Tumors, Nature Reports Stem Cells 2007		
434.	National Geographic January 26, 2017 Article re Human-Pig Hybrid Created in the Lab-Here are the Facts		
435.	Chrzanowski, W. et al. Can Stem Cells Beat COVID-19: Advancing Stemm Cells and Extracellular Vesicles Toward Mainstream Medicine for Lung Injuries Associated with SARS-CoV-2 Infections,		
436.	Eguizabal, C. et al. Two Decades of Embryonic Stem Cells: A Historical Overview, Human Reproduction Open 2018		
437.	Kumar, R. et al. Stem Cells: An Overview with Respect to Cardiovascular and Renal Disease, J Nat Sci Biol Med. 2010 Jul-Dec; 1(1): 43-52		
438.	Business Wire November 15, 2019 Article re Lineage Cell Therapeutics Provides Update on SCiStar Clinical Study and OPC1 Spinal Cord Injury Program		
439.	Makkar, R. et al. Intracoronary Cardiosphere-Derived Cels for Heart Regeneration After Myocardial Infarction (CADUCEUS): A Prospective, Randomised Phase 1 Trial, Frontiers in Bioengineering and Biotechnology 2020		
440.	Malliaras, K. et al. Cardiomyocyte Proliferation and Progenitor Cell Recruitment Underlie Therapeutic Regeneration After Myocardial Infarction in the Adult Mouse Heart, EMBO Mol Med (2013) 5, 191-209Lancet 2012;379;895-904		
441.	UCLA June 23, 2020 Article re Researchers Use Stem Cells to Model the Immune Response to COVID-19		

Ex. No.	Description	Date Identified	Date Admitted
442.	Rosenzweig, E. et al. Restorative Effects of Human Neural Stem Cells Grafts to the Primate Spinal Cord, <i>Nat Med.</i> 2018 May;24(4):484-490		
443.	Schukking, M. et al. Direct Generation of Human Cortical Organoids from Primary Cells, Stem Cells and Development 2018;27:1549-1556		
444.	Schwartz, S. et al. Human Embryonic Stem Cell-Derived Retinal Pigment Epithelium in Patients with Age-Related Macular Degeneration and Stargardts Macular Dystrophy: Follow-up of Two Open-Label Phase 1/2 Studies, <i>Lancet</i> 2015;385:509-516		
445.	<b>California Institute for Regenerative Medicine March 27, 2020 Article re Stem Cell Agency Board Approves \$5 Million in Emergency Funding for COVID-19 Research</b>	5/4/2021 stip	5/4/2021 stip
446.	Tachibana, M. et al. Human Embryonic Stem Cells Derived by Somatic Cell Nuclear Transfer, <i>Cell.</i> 2013 June 6; 153(6): 1228-1238		
447.	Takasato, M. & Little M. A Strategy for Generating Kidney Organoids: Recapitulating the Development in Human Pluripotent Stem Cells, <i>ScienceDirect</i> 2016;420:210-220		
448.	Nature Research March 5, 2019 Article re Second Patient Free of HIV After Stem-Cell Therapy		
449.	Wilkinson, D. et al. Development of a Three-Dimensional Bioengineering Technology to Generate Lung Tissue for Personalized Disease Modeling, <i>Stem Cells Translational Medicine</i> 2017;6:622-633		
450.	UCLA Broad Stem Cell Research Center September 15, 2016 Article re Researchers Use Stem Cells to Grow Mini 3-D Lung-in-a-Dish		
451.	Wittich, C. et al. Ten Common Questions (And Their Answers) About Off-Label Drug Use, <i>Mayo Clin Proc.</i> 2012;87(10):982-990		

Ex. No.	Description	Date Identified	Date Admitted
452.	The Nobel Prize in Physiology or Medicine 2012 Press Release		
453.	<b>Cell Surgical Network Video: How to Isolate SVF</b>	5/4/2021 stip	5/4/2021 stip
454.	Somoza, R. et al. Roles for mesenchymal stem cells as medicinal signaling cells, Nat Protoc. 2016 Jan;11 (1).		
455.	[Exhibit withdrawn]		
456.	<b>California Institute of Regenerative Medicine Disease Programs</b> <a href="https://www.cirm.ca.gov/patients/disease-information">https://www.cirm.ca.gov/patients/disease-information</a>	5/4/2021 stip	5/4/2021 stip
457.	Minev, B. et al. First-in-human study of TK-positive oncolytic vaccinia virus delivered by adipose stromal vascular fraction cells, J. Transl. Med. 17:271 (2019)	5/7/2021	

Respectfully Submitted,

DATED: May 3, 2021

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**UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA**

## LIST OF EXHIBITS AND WITNESS - CONTINUED

Case No. EDCR18-01005-JGB(KKx)

Title: USA v. CALIFORNIA STEM CELL TREATMENT....

[illegible]

1 DATED: May 3, 2021

JONES DAY

2 By: /s/ Celeste M. Brecht

3 Celeste M. Brecht

4 Ramanda R. Luper

5 VENABLE LLP

6 Matthew M. Gurvitz

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8 *hac vice*)

9 Attorneys for Defendants

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11 TREATMENT CENTER, INC., CELL

12 SURGICAL NETWORK

13 CORPORATION, ELLIOT B. LANDER,  
14 M.D. and MARK BERMAN, M.D.

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11 UNITED STATES DISTRICT COURT  
12 FOR THE CENTRAL DISTRICT OF CALIFORNIA  
13 EASTERN DIVISION  
14

15 UNITED STATES OF AMERICA,

16 Plaintiff,

17 v.

18 CALIFORNIA STEM CELL  
TREATMENT CENTER, INC.,  
19 *et al.*

20 Defendants.  
21  
22  
23  
24  
25  
26  
27  
28

No. 5:18-CV-01005-JGB-KKx

**PLAINTIFF'S WITNESS LIST**

Trial Date: May 4, 2021

Honorable Jesus G. Bernal  
United States District Judge



<u>Witness Name</u>	<u>Date Called To Testify</u>
1. Christopher C. Joneckis, Ph.D.	5/4/2021
2. William Frederick Lagud, Jr.	5/4/2021
3. Cynthia Jim	5/11/2021
4. Michele L. Forster, Ph.D.	5/5/2021
5. Darla J. Christopher	5/5/2021
6. Paul Knoepfler, Ph.D.*	5/5/2021
7. Elliot B. Lander, M.D.	
8. Mark Berman, M.D.*	
9. Sean T. Berman*	
10. Audrey Fianza*	
11. Judi E. Meglio*	
12. Larissa Lapteva, M.D.	5/5/2021/ 5/6/2021/ 5/13/2021
13. Carolyn Yong, Ph.D.	5/7/2021 / 5/13/2021

Pursuant to Local Rule 16-5, the Government has placed an asterisk (\*) next to the names of witnesses who the Government may call only if the need arises.

Moreover, at this time the Government does not intend to call the following witnesses from its original witness list: (1) Daniel Cline, (2) Shawntae Dowell, (3) Dr. John M. Feller, (4) Doran L. Fink, M.D., Ph.D., (5) Bernadette M. Greenwood, (6) Sam Labinjo, (7) Randa F. Melhem, Ph.D., (8) Catherine Quinlan, (9) Karlton Watson, and (10) Brittany White [*sic* – Whitley].

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CELL SURGICAL NETWORK  
CORPORATION, ELLIOT B. LANDER, M.D.  
and MARK BERMAN, M.D.

**UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA  
EASTERN DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

v.

CALIFORNIA STEM CELL  
TREATMENT CENTER, INC., a  
California corporation, CELL  
SURGICAL NETWORK  
CORPORATION, a California  
corporation, and ELLIOT B. LANDER,  
M.D., MARK BERMAN, M.D.,  
individuals,

Defendants.

CASE NO. 5:18-CV-01005-JGB-KK

Hon. Jesus G. Bernal  
Riverside, Courtroom 1

**DEFENDANTS' WITNESS LIST**

Final Pretrial Conf.: May 11, 2020

Action Filed: May 9, 2018  
Trial Date: May 26, 2020

Witness Name	Date Called to Testify
1. Mark Berman, M.D.	5/11/2021 / 5/12/2021
2. Elliot Lander, M.D.	5/12/2021 / 5/13/2021
3. Sean Berman	
4. Lola Reid, Ph.D.	5/12/2021

Dated: April 20, 2020

VENABLE LLP

By: /s/ Celeste M. Brecht

Celeste M. Brecht

Matthew M. Gurvitz

Ramanda R. Luper

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